

U.S. Department
of Transportation
Research and
Special Programs
Administration

APR 15 2004

400 Seventh St., S.W. Washington, D.C. 20590

Ref. No. 03-0294

Mr. Jeff Henderson Lead Technical Consultant RCS, Inc. - Ohio 950 Taylor Station Road Suite M Gahanna, OH 43230

Dear Mr. Henderson:

This responds to your letter regarding consumer commodities under the Hazardous Materials Regulations (HMR;49 CFR Parts 171-180). Specifically, you are requesting confirmation that a medical product, containing two flammable liquid components regulated under the HMR and being distributed by Baxter Healthcare Corporation, is eligible for the consumer commodity exception.

The answer is yes. The definition of consumer commodity includes drugs or medicines when packaged according to the appropriate limited quantity provisions for the hazard class and packing group assigned to the material(s). It is our opinion that your client's product meets these requirements and may be offered for transportation as a consumer commodity.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

Hattie L. Mitchell

Chief, Regulatory review and Reinvention Office of Hazardous Materials Standards



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171.8



November 11, 2003

United States Department of Transportation Research and Special Programs Administration 400 7th Street SW

Washington D.C. 20590-0001

Attn: Edward Mazzullo - Director, Office of Hazardous Materials Standards

Stevens
§ 171.8

Consumer Commodity

Definitions
03-0294

RE: Letter of Interpretation under the Consumer Commodity Definition

Dear Mr. Mazzullo,

The following, requests a letter of interpretation regarding the applicability of the definition of a Consumer Commodity as stated in 49 CFR 171.8. RCS, Inc.'s client, Baxter Healthcare Corporation, distributes medical products. The product requesting interpretation is an Anesthesia Tray, which may contain one of two hazardous components, a Compound Benzoin Tincture or a DuraPrep Applicator.

Compound Benzoin Tinctures consist of 0.67 ml, of a 75-80% Ethyl Alcohol solution with a flashpoint of 50° F. This product is contained within a glass ampul, placed in a sealed plastic applicator tube for use in a clinical setting. The DuraPrep Applicators are packaged in a quantity of 6 ml, and contain 60-100% Isopropyl Alcohol and 0.7% Iodine, with a flashpoint of 55-85° F. The applicators are packaged in an inner glass vial contained within a plastic housing. Packaging of the anesthesia trays, explained above, are capable of containing 100% of the hazardous materials within the inner packaging.

One of the above two products is combined with other non-hazardous materials utilized in a clinical setting for administering anesthesia to a patient. Products are placed in sealed plastic, within a tray for delivery to healthcare professionals for use. When shipped, anesthesia trays are overpacked in strong fiberboard packages, able to withstand shocks and stresses inherent during normal transportation activities.

A letter of interpretation is requested to allow for shipment of the above products as Consumer Commodity, ORM-D materials. While the above products are manufactured and utilized in a clinical setting, the type of packaging utilized for the products is suitable for household or personal use.

Under the current definition, a Consumer Commodity means a material that is packaged and distributed in a form intended or suitable for sale through retail

sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. This term also includes drugs and medicines.

It is the opinion of Baxter Healthcare Corporation, and RCS, Inc., that the above mentioned products can be classified as Consumer Commodity, ORM-D materials. Therefore, it is requested that a letter of interpretation be formed to acknowledge if the above products may be shipped as Consumer Commodity, ORM-D materials under USDOT Hazardous Materials Regulations.

Additional information regarding the above products can be obtained from the following sources.

Bill Withrow
Manager, Environmental, Health & Safety
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
847-473-6173

Jeff Henderson Lead Technical Consultant RCS, Inc.-Ohio 950 Taylor Station Road, Suite M Gehanna, OH 43230 614-552-8530 x 31

Upon determination and completion of a letter of interpretation, please reply to the above personnel at the listed addresses. Your cooperation and timeliness are greatly appreciated.

Sincerely,

Jeff Henderson

Lead Technical Consultant

RCS, Inc.-Ohio 614-552-8530 x 31

jehenderson@4rcs.com